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| 10/682,310 | 10/08/2003 | Mattias Karlsson | 58282 (47137) | 7321 |

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| EXAMINER | |
|---|---|
| PRICE, CRAIG JAMES | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/682,310 | KARLSSON ET AL. | |
| | Examiner | Art Unit | |
| | Craig Price | 3753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *28,29,35,37,38,40-51 and 53-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,35,37,38,40-51 and 53-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 March 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

### *Drawings*

1. Applicant's amendment overcomes the drawing objections.

### *Claim Objections*

2. Claim 55 is objected to because of the following informalities: Line 1, "55" should be - - 54 - -. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28,29,35,37,38,40,41-50 and 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 28,29, 48, 49 and 57 recite the limitation "a substantially separate aqueous stream" is unclear as to if the streams are separate or not. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 57 is rejected under 35 U.S.C. 102(e) as being anticipated by Chiu et al. (7,470,518, available with the filing date of the provisional application 60/356,377)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 57, Chiu et al. disclose a system comprising a macroscale device which is interfaced with a microfluidic device using double-sided tape to form a stable association between the microfluidic device and the macroscale device, wherein the double sided tape comprises a first adhesive surface which associates with the macroscale device and a second adhesive surface which associates with the microfluidic device (Col. 58, Lns. 52-67), wherein the microfluidic device has at least three microchannels suitable for containing a fluid stream, and at least three sensor chambers each containing at least one sensor, and wherein each microchannel comprises an outlet for delivering a substantially separate aqueous stream into the sensor chamber (Col. 2, Lns. 11-18), and wherein the microchannels correspond in number to the number of wells in a microtiter plate ("the microchannels correspond in number… microtiter plate", is considered as functional language and not given patentable weight. "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 28, 29, 38, 40, 48, 49, 51, 52, 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Crivelli (6,869,273).

Regarding claims 28, 29, 48 and 49, Benavides et al. disclose, as shown in Figure 21 a macroscale device (110,120 having a tubing outer diameter of 1/16 of an inch), which is interfaced with a microfluidic (100) device using double-sided tape (26, Col.8, Lns. 30-34) or transfer tape (Col.7, Lns. 61-65) to form a stable association between the microfluidic device and the macroscale device, wherein the double sided tape comprises a first adhesive surface which associates with the macroscale device and a second adhesive surface which associates with the microfluidic device, wherein the microfluidic device has a plurality of microchannels (Col.11, Lns. 58-63, Col. 12, Lns. 6-11) suitable for containing a fluid stream, and wherein each microchannel

comprises an outlet (Col. 11, Lns. 63-65) “for delivering a substantially separate aqueous stream into the sensor chamber”, and at least one sensor (Col. 11, Lns. 58-63). Regarding "for delivery …sensor chamber", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Benavides et al. disclose having a sensor but does not explicitly teach having at least one sensor chamber containing at least one sensor.

Crivelli discloses a micromechanical device which teaches the use of at least one sensor chamber containing at least one sensor (Col. 6, Lns. 22-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a chamber containing at least one sensor as taught by Crivelli into the device of Benavides et al. in order to measure some characteristic of the fluid (Col. 6, Lns. 23-25).

Regarding claim 37, Benavides et al. disclose that the one or more sensor chambers is for containing one or more cells (Col.11, Lns. 54-56).

Regarding claim 38, Benavides et al. disclose that the microfluidic device comprises at least one electrical element (58) “for performing planar patch clamp analysis”. The limitation “for performing…” is considered as an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 40, Benavides et al. disclose that the macroscale device comprises a pump head (120) connectable to a pressurized air supply (Col. 11, Lns. 53-54, "Fluids processed by the device can be "gaseous"...).

Regarding claim 51, Benavides et al. disclose a pressure chamber (20) between the macroscale device and the microfluidic device.

Regarding claim 52, Benavides et al. disclose that a system comprising a pump head device (110,120) which is interfaced with a microfluidic device (100) using double-sided tape (26) to form a stable association between the microfluidic device and the pump head device, wherein the double sided tape comprises a first adhesive surface which associates with the pump head device and a second adhesive surface which associates with the microfluidic device, and wherein a pressure chamber (20) is between the pump head device and the microfluidic device as shown in Figure 21, and the microfluidic device comprises a plurality of microchannels (Col. 12, Lns. 7 – 11, "Sacrificial silicon dioxide is used to define microfluidic channels…").

Regarding claim 53, Benavides et al. disclose that the system comprises at least three microchannels as shown in Figure 23.

Regarding claim 56, Benavides et al. discloses that the system comprises three of more delivery channels (as shown in Figure 23) delivering one or more of a sample (Col. 11, Lns. 54-56), an agonist, or an agonist.

7. Claims 35 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Crivelli (6,869,273) and further in view of Pfost (5,104,621).

Benavides et al. disclose all of the features of the claimed invention although is silent to a system, wherein the microchannels correspond in number to the number of wells in a microtiter plate, and, wherein the microchannels connect to reservoirs in the microfluidic device and wherein the center-to-center distance of each reservoir corresponds to the center-to-center distance of the wells in the microtiter plate.

Pfost et al. disclose an analytical automated chemistry processing center which teaches the use of a microtiter plate (Col. 11, Lns. 45-48).

It would have been obvious to one of ordinary skill in the art at the time of invention to utilize microtiter plates as taught by Pfost et al. into the system of Benavides et al. to have a system wherein the microchannels correspond in number to the number of wells in an industry-standard microtiter plate, and, wherein the microchannels connect to reservoirs in the microfluidic device and wherein the center-to-center distance of each reservoir corresponds to the center-to-center distance of the wells in the microtiter plate, in order to have an automated material handling system which could transfer the samples from one well of one microtiter plate to a different well in another microtiter plate depending on the type of analysis desired (Col. 11, Lns. 45-53).

8. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Crivelli (6,869,273) and further in view of Bjornson et al. (6,103,199).

Benavides et al. have disclosed all of the features of the claimed invention although is silent to the system having the macroscale surface interfaced with a microfluidic surface of a device being a pump thereby being selected from the group consisting of a pump head, pump, degasser, flow meter, injector manifold, a pressure sensor, flow cell, concentration manifold or cartridges, a fitting or connector, a mixer, a compressor, an ultrasonic bed, an extractor, a focusing device, a dialysis chamber, an absorption chamber, a metabolite chamber, a toxicity chamber, a cell chamber, a detector, an RFID tag, a reagent vessel, a separation column, a focusing column, a size exclusion column, an ion-exchange columns, affinity columns, solid-phase extraction beds, a filter, a sieve, a frit, a depth filter, a heater, a heat exchanger, a cooler, a magnetic field generator, electric field generator, electroporation device, patch clamp pipette, and one or more connections thereto, and that the detector is a fluorescence flow cell which is selected from the group consisting of a UV/Visible absorbance flow cell, a fluorescence flow cell, a conductivity flow cell, an electrochemical detector, a plasma detector, surface plasmon resonance detector and a mass spectrometry detector and that the detector is an optical sensor such, selected from the group consisting of a flow meter, a pressure transducer, a temperature sensor, a chemical sensor, an acoustic sensor, a color sensor, an optical sensor, a bar code sensor, a photothermal sensor, a photoacoustic sensor, and an RFID tag.

Bjornson et al. discloses a capillary electroflow apparatus which teaches the use of an optical detection device such as ultraviolet or fluorescence spectrometer (Col. 24, Lns. 1-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an ultraviolet optical detection device as taught by Bjornson et al. into the assembly of Benavides et al. in order to "read the different types of substances being moved to different portions of the medium", so that "the information can be sent to the computer, which can adjust the speed of the waves or voltage distribution profiles being generated in order to more precisely fine tune the resolution of the substances being moved through the medium" (Col. 24, Lns. 6-12).

9. Claims 44,45,49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Crivelli (6,869,273) and further in view of Crandall et al. (6,352,766).

Benavides et al. have disclosed all of the features of the claimed invention although is silent to at least one adhesive side of the tape surface covered by a release liner prior to adhering the device surface of the macroscale or microfluidic device and adhesives on each side of the double sided tape comprise different types of adhesive and transfer tape forming a stable association between the microfluidic device and the macroscale device, wherein the transfer tape comprises a backing to which an adhesive surface is seperably attached and wherein a bond between the adhesive and the

backing is weaker than a bond between the adhesive and the macroscale or microfluidic surface.

Crandall et al. disclose a low adhesion material which teaches a device as having at least one adhesive side of the tape surface is covered by a release liner (Col. 5, Lns. 38-41) prior to adhering the device surface of the macroscale or microfluidic device and adhesives on each side of the double sided tape comprise different types of adhesive (Col. 5, Lns. 41-45).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ a system having at least one adhesive side of the tape surface is covered by a release liner prior to adhering the device surface of the macroscale or microfluidic device and adhesives on each side of the double sided tape comprise different types of adhesive and transfer tape forming a stable association between the microfluidic device and the macroscale device, wherein the transfer tape comprises a backing to which an adhesive surface is seperably attached and wherein a bond between the adhesive and the backing is weaker than a bond between the adhesive and the macroscale or microfluidic surface as taught by Crandall et al. onto the device of Benavides et al. in order to permit the easy removal of the liner from the coated article (Col.1, Lns 21-30).

10. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Crivelli (6,869,273) and further in view of DiZio et al. (6,455,152).

Benavides et al. have disclosed all of the features of the claimed invention although is silent to the system having the adhesive on the tape is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive.

Dizio et al. disclose an adhesive coating article which teaches the use of the adhesive on the tape is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive (Col. 5, Lns. 39-41).

It would have been obvious to one of ordinary skill in the art at the time of invention to utilize an adhesive on the tape which is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive as taught by Dizio et al. onto the system of Benavides et al. in order to reduce the surface contact between the transfer surface and the adhesive (Col. 5, Lns. 9-20) to have a better transfer of adhesive during the manufacturing process when joining the microfluidic and macroscale devices.

11. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Crivelli (6,869,273) and further in view of Chiu et al. (7,470,518, available through the provisional application 60/356,377).

Benavides et al. disclose all of the features of the claimed invention although is silent to a system having the sensor be a cell based biosensor and in which the cell based biosensor is a receptor.

Chiu et al. disclose a microfluidic device which teaches the use of a biosensor that is a receptor, as disclosed in the originally filed specification in the provisional application on page 30, the GPCR sensor is a cell based biosensor which is a receptor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a cell based biosensor which is a receptor as taught by Chiu et al. in order to measure the desired characteristic of the sample.

12. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Crivelli (6,869,273) and further in view of Stanto et al. (7,125,660, available through the application 09/952,680).

Benavides et al. disclose all of the features of the claimed invention although is silent to a system having the sensor be a cell based biosensor and in which the cell based biosensor is a receptor.

Stanton et al. disclose a microfluidic device which teaches the use of a biosensor that is a receptor, as disclosed in the originally filed specification in the provisional application on page 57, lines 6-13, the GPCR sensor is a cell based biosensor which is a receptor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a cell based biosensor which is a receptor as taught by Stanton et al. in order to measure the desired characteristic of the sample.

### *Double Patenting*

13. Applicant is advised that should claims 28 and 29 be found allowable, claims 48 and 49 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### *Response to Arguments*

14. Applicant's arguments with respect to claims 28, 29, 35, 37, 38, 40-51, 53-58 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Craig Price whose telephone number is (571) 272-2712. The examiner can normally be reached on 7AM - 5:30PM M-R, Increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on (571) 272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CP/ 2 July 2009 /John Rivell/
Primary Examiner, Art Unit 3753

/C. P./
Examiner, Art Unit 3753